From: Fulford, Greg
To: Lanzisera, Penny
Subject: [External_Sender] RE: Request for Additional Information
Date: Tuesday, June 06, 2017 1:26:32 PM

54-28275-02MD
03030793

Hello Penny,

I thank you for your feedback on our application from May 24, 2017. We have had a deeper look into our request to add the C-446 source to our -02MD license. Given that we do not have any immediate requirement to use this source for medical applications we would like to withdraw our request at this time. We have not had any discussions with FDA about registering our source as a medical device, nor do we have any immediate plans to incorporate this source into an approved medical device in the U.S. Should things change in the future, we will re-apply with your office.

Regards,

Greg Fulford ¦ Nuclear Transportation Specialist
Nordion ¦ 447 March Road ¦ Ottawa, ON K2K 1X8
Tel: 613 592 3400 ext 2658 ¦ Fax: 613 592 2006
www.nordion.com ¦ greg.fulford@nordion.com

-----Original Message-----
From: Lanzisera, Penny [mailto:Penny.Lanzisera@nrc.gov]
Sent: Tuesday, June 06, 2017 12:39 PM
To: Fulford, Greg
Subject: FW: Request for Additional Information

Good afternoon. Can you confirm receipt of the below? Also, I have not received confirmation from the sealed source and device review group. I will let you know when they answer.

Penny

-----Original Message-----
From: Lanzisera, Penny
Sent: Wednesday, May 24, 2017 2:53 PM
To: 'Fulford, Greg' <Greg.Fulford@nordion.com>
Subject: Request for Additional Information

Licensee: Nordion (Canada)
License No. 54-28275-02MD
Docket No. 03030793
Mail Control 594718

In order to continue our review of your amendment request to add the new source model to your Medical Distribution license, we require the following additional information:

As requested in Appendix U of NUREG-1556, Volume 12, please provide the following additional information:

1.the maximum activity in each source, and the anticipated use of the sources. If the sealed sources are usually used in a device, specify the manufacturer's name and the model number of the device (e.g., ViewRay).

2.confirm that the activity per source will not exceed the maximum activity listed on the approved certificate of

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NMSS/RGN1 MATERIALS-002

registration issued by NRC (when issued).

As requested in NUREG-1556, Vol. 13, please provide the following additional information:

1.Submit copies or facsimiles of the labels that will accompany the sources and specify where each label will be placed (e.g., on the source shield).

2.Submit copies of all leaflets and brochures that will accompany the sources.

3.Provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source to be safe for medical use (e.g., 510(K) approval).

4.For shipping containers used, describe the type of shipping container, container shielding, maximum radiation level expected for a fully loaded container, and maximum activity allowed per container.

5.If you do not plan to offer a source return program, so state; no additional information is necessary. However, if you offer a source return program, you must have developed, and must supply to your customers, sufficiently detailed instructions (including instructions on labeling and shipping documents) to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations. You must also submit to NRC copies or facsimiles of all forms, labels, and instructions that you will provide to customers for shipping sources back to your facility separately licensed for possession. As a minimum, the instructions must:

a.Establish the user's responsibility and liability as the shipper;
b.Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
c.Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189.

This discussion of the customer's responsibilities should include (but is not limited to):
* The requirements to survey and wipe-test packages;
* The distance at which to survey packages;
* The action levels for the package wipe-test results;
* The dose rate limitations on the particular shipping label that you will provide; and
* The need for sealing tape or another mechanism to fulfill the security seal requirement.

As discussed previously, the sealed source review is underway. To complete our review, we need the final sealed source review and the additional information described above. You may submit the above information to my attention via a signed pdf letter; signed by senior management. Alternatively, you may fax the signed letter to 610-337-5269. Please reference Mail Control No. 594718 in your reply. Sincerely,

Penny Lanzisera
Senior Health Physicist
U.S. NRC, Region I